Monoclonal Antibody Outpatient Treatment: Sotrovimab

December 16, 2021

Alberta Health Services

Sotrovimab

December 16, 2021

What is Sotrovimab?

A Monoclonal antibody that prevents the virus from entering healthy cells within the body.

Approved for outpatient use in Alberta for:

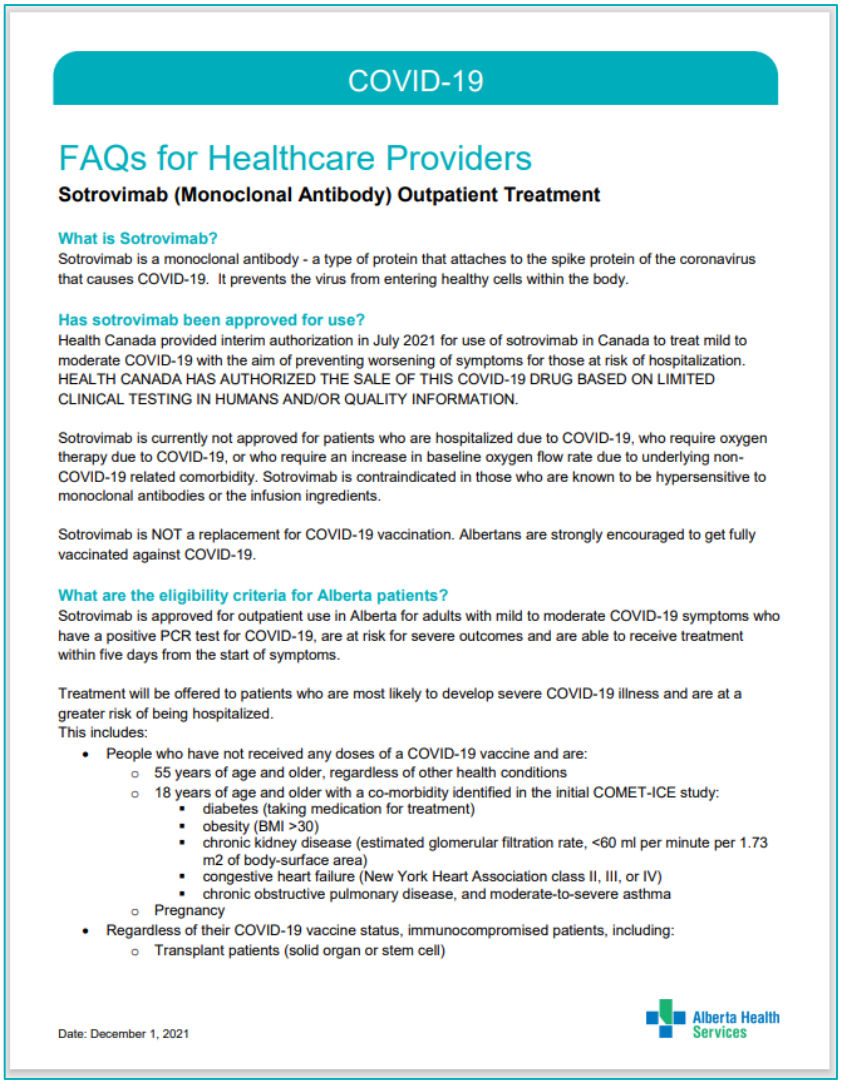
- Adults with mild to moderate COVID-19 symptoms who have a positive PCR test for COVID-19; Are at risk of severe outcomes; and
- Are able to receive treatment within 5 days from the start of symptoms.

Treatment is available for:

1. Unvaccinated:
- People aged 55 years and older
- People aged 18 years and older with a pre-existing health condition
- Pregnant

2. Immunocompromised
- Vaccinated or unvaccinated

[Outpatient Treatment for COVID-19 | Alberta Health Services]



COVID-19

FAQs for Healthcare Providers

Sotrovimab (Monoclonal Antibody) Outpatient Treatment

What is Sotrovimab?
Sotrovimab is a monoclonal antibody - a type of protein that attaches to the spike protein of the coronavirus that causes COVID-19. It prevents the virus from entering healthy cells within the body.

Has sotrovimab been approved for use?
Health Canada provided interim authorization in July 2021 for use of sotrovimab in Canada to treat mild to moderate COVID-19 with the aim of preventing worsening of symptoms for those at risk of hospitalization. HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 DRUG BASED ON LIMITED CLINICAL TESTING IN HUMANS AND/OR QUALITY INFORMATION.

Sotrovimab is currently not approved for patients who are hospitalized due to COVID-19, who require oxygen therapy due to COVID-19, or who require an increase in baseline oxygen flow rate due to underlying non-COVID-19 related comorbidity. Sotrovimab is contraindicated in those who are known to be hypersensitive to monoclonal antibodies or the infusion ingredients.

Sotrovimab is NOT a replacement for COVID-19 vaccination. Albertans are strongly encouraged to get fully vaccinated against COVID-19.

What are the eligibility criteria for Alberta patients?
Sotrovimab is approved for outpatient use in Alberta for adults with mild to moderate COVID-19 symptoms who have a positive PCR test for COVID-19, are at risk for severe outcomes and are able to receive treatment within five days from the start of symptoms.

Treatment will be offered to patients who are most likely to develop severe COVID-19 illness and are at a greater risk of being hospitalized.
This includes:

- People who have not received any doses of a COVID-19 vaccine and are:
  - 55 years of age and older, regardless of other health conditions
  - 18 years of age and older with a co-morbidity identified in the initial COMET-ICE study:
    - diabetes (taking medication for treatment)
    - obesity (BMI >30)
    - chronic kidney disease (estimated glomerular filtration rate, <60 ml per minute per 1.73 m2 of body-surface area)
    - congestive heart failure (New York Heart Association class II, III, or IV)
    - chronic obstructive pulmonary disease, and moderate-to-severe asthma
  - Pregnancy
- Regardless of their COVID-19 vaccine status, immunocompromised patients, including:
  - Transplant patients (solid organ or stem cell)

Date: December 1, 2021

Alberta Health Services

Referral Process

Referral Process for All Albertans

- Eligibility for treatment is based off a **positive RT-PCR test.**
- Should a patient have a positive rapid test in the community, a PCR test must be done as soon as possible for eligibility.
- Patients a positive RT-PCR and meet an initial eligibility criteria must call into HealthLink for further eligibility screening.
- If patients are within the Mobile Integrated Health Community Paramedic catchment area and capacity, a referral will be sent to the MIH team and care will be provided within the patient's home
- Eligible patients outside MIH area or capacity are referred to the monoclonal antibody physician (MAP) group who confirm eligibility, obtain consent and provide referral.
- All referrals from the MAP group are sent to RAAPID for site referral. RAAPID has a complete list of all sites providing treatment within the province.
- When sites receive a referral, local process for contacting the patient, booking the appointment and completion of infusion are followed.
- Depending on location, communities will be required to assist with transportation arrangements to the infusion site.

Referral Process for Delivery on First Nations

- Eligibility for treatment is based off a **positive RT-PCR test.**
- Should a patient have a positive rapid test in the community, a PCR test must be done as soon as possible for eligibility.
- Patients who are positive and meet an initial eligibility criteria will be referred to the physician/NP within the First Nations site.
- The First Nation Physician/NP will assess the patient for eligibility, obtain consent and provide prescribe the treatment.
- The patient will be directed to either attend to the First Nations clinic for treatment or will have the treatment provided within their home.

Registration and Nursing Process

Registration Process

1. Patients shall arrive wearing a mask and will maintain physical distancing, as explained during booking process.

2. Patients shall perform hand hygiene an change in to a facility provided mask upon entry.

3. The practitioner administering the medication shall escort the patient through the facility in accordance with IPC guidelines.

4. The infusion nurse shall don appropriate PPE for escorting patient (including eye protection, mask, gloves and gown while escorting the patient through the facility and during patient care.

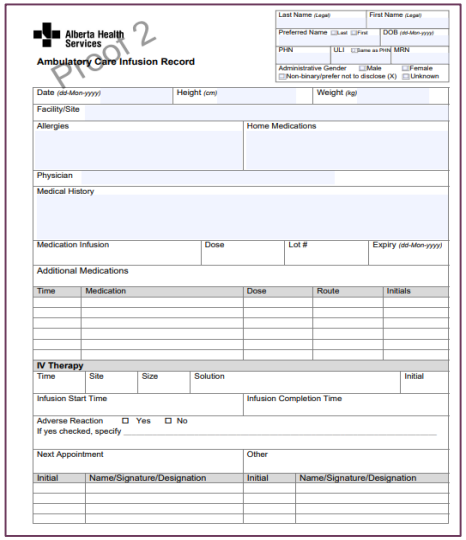
5. Patients shall be registered as per site designated process. The patient shall be registered under the ordering physician/NP.

Nursing Process- Pre- Administration

1. Infusion Nurse (IN) shall obtain baseline assessment and vital signs *prior* to the initiation of treatment. *Should a patient refuse consent at time of administration, such shall be documented in patient chart and patient escorted to the exit. IN shall notify MAP physician group via email*

2. Any patient(s) who are found to be in a declining state of health and requiring acute care shall be take to the Emergency Department. *The ordering physician shall be notified and the infusion nurse shall document the inability to provide the medication. The ordering physician (if out of that zone/site) will contact the emergency physician to organize a patient handover.*

3. Documentation shall occur on the "**Ambulatory Care Infusion Record**" documentation tool.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Ambulatory Care Infusion Record

Proof 2

Last Name (Legal) | First Name (Legal)

Preferred Name | DOB (dd-Mon-yyyy)

PHN | ULI | MRN

Administrative Gender: Male, Female, Non-binary/prefer not to disclose (X), Unknown

Date (dd-Mon-yyyy) | Height (cm) | Weight (kg)

Facility/Site

Allergies | Home Medications

Physician

Medical History

Medication Infusion | Dose | Lot # | Expiry (dd-Mon-yyyy)

Additional Medications

Time	Medication	Dose	Route	Initials

IV Therapy

Time	Site	Size	Solution	Initial

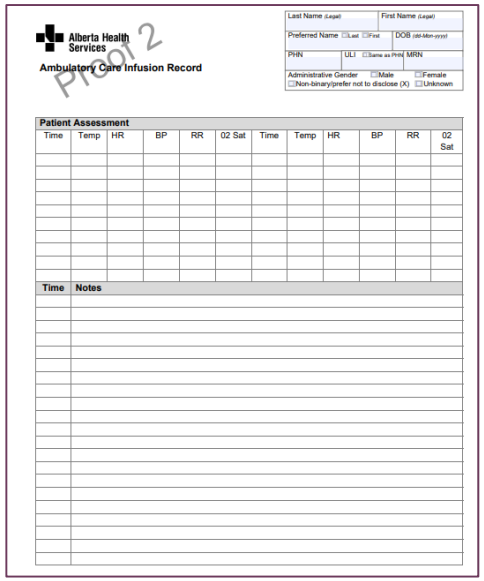
Infusion Start Time | Infusion Completion Time

Adverse Reaction ☐ Yes ☐ No

If yes checked, specify

Next Appointment | Other

Initial	Name/Signature/Designation	Initial	Name/Signature/Designation


Alberta Health Services

Ambulatory Care Infusion Record

Proof 2

Last Name (Legal) | First Name (Legal)

Preferred Name | DOB (dd-Mon-yyyy)

PHN | ULI | MRN

Administrative Gender: Male, Female, Non-binary/prefer not to disclose (X), Unknown

Patient Assessment

Time	Temp	HR	BP	RR	02 Sat	Time	Temp	HR	BP	RR	02 Sat

Time	Notes

Nursing Process - Reconstitution

1. Infusion Nurse (IN) shall initiate intravenous.
2. Infused as an intermittent IV infusion over 60 minutes.
3. For adults 40kg or more; 500mg IV single dose vial.
4. Sotrovimab vial removed from refrigerator and allow to equilibrate to room temp for approx. 15 minutes before prep.
5. GENTLY swirl vial several times before use. DO NOT SHAKE.
6. Withdraw 8mL (500mg) from vial of Sotrovimab.
7. Inject 8 mL of Sotrovimab into 0.9% normal saline infusion bag. *Discard any unused portion left in vial. Vial is Single Use Only.*
8. Prior to administration, gently rock IV infusion bag by hand ~ 3 to 5 times. Do not Invert infusion bag. *Product contains no preservative; and therefore, the diluted Infusion solution shall be administered immediately*.
9. If immediate administration is not possible, refer to AHS product parenteral manual.

Nursing Process - Administration

1. Administered with a 0.2 or 0.2 micron filter.
2. Attach infusion set to prepared IV bag
3. Prime infusion set
4. Administer as an IV infusion over 60 minutes.
5. Infusion nurse shall document time of initiation of infusion.
6. IN shall monitor patient(s) and complete vital signs every 15 minutes during infusion and for 60 minutes afterwards.
7. Once infusion is completed, IN shall document time of completion.
8. Completed documentation should be scanned and sent to the email for the MAP group at:

COVID Monoclonal Antibody Therapy

COVID.MonoclonalAntibodyTherapy@albertahealthservices.ca

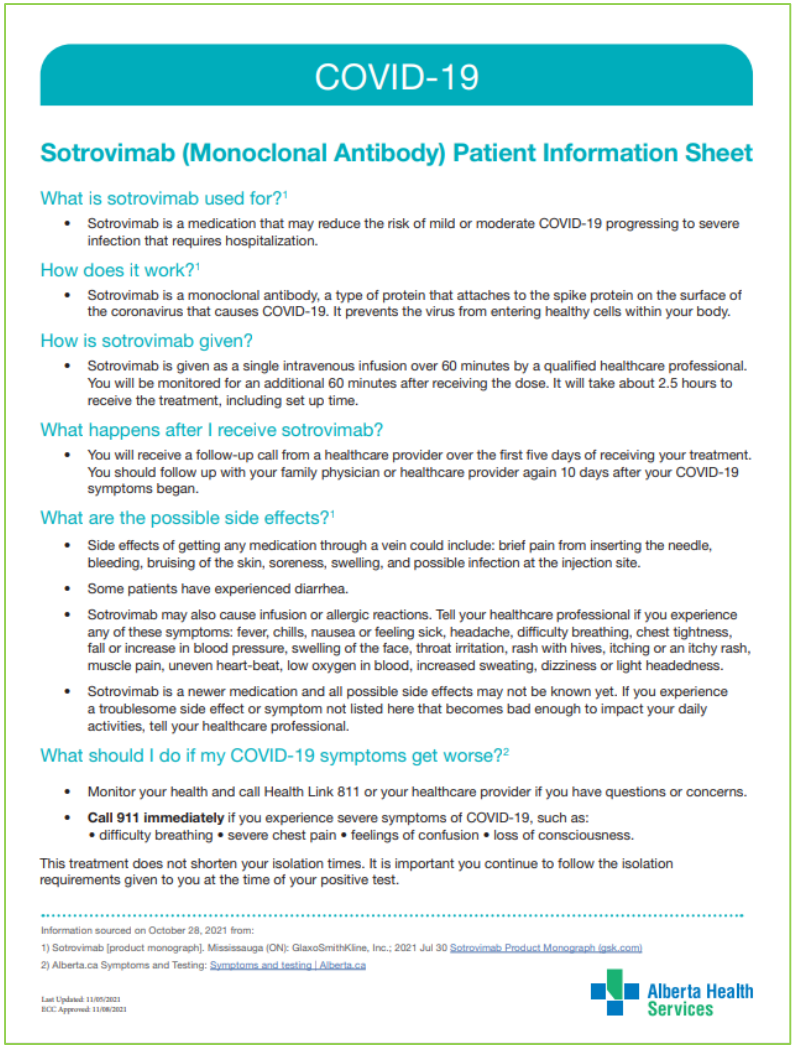
Discharge Process

Discharge Process

1. Infusion Nurse (IN) will **provide patient(s) with follow up information and discharge instructions following administration** and notify the patient to expect a follow up phone call from the MAP physician or FN physician the next day.

2. IN shall escort patient(s) to entrance following discharge in accordance with IPC COVID discharge guidelines.

3. All patients charts shall be completed and sent to medical records following completion, and prior to the end of the day.



COVID-19

Sotrovimab (Monoclonal Antibody) Patient Information Sheet

What is sotrovimab used for?[1]

- Sotrovimab is a medication that may reduce the risk of mild or moderate COVID-19 progressing to severe infection that requires hospitalization.

How does it work?[1]

- Sotrovimab is a monoclonal antibody, a type of protein that attaches to the spike protein on the surface of the coronavirus that causes COVID-19. It prevents the virus from entering healthy cells within your body.

How is sotrovimab given?

- Sotrovimab is given as a single intravenous infusion over 60 minutes by a qualified healthcare professional. You will be monitored for an additional 60 minutes after receiving the dose. It will take about 2.5 hours to receive the treatment, including set up time.

What happens after I receive sotrovimab?

- You will receive a follow-up call from a healthcare provider over the first five days of receiving your treatment. You should follow up with your family physician or healthcare provider again 10 days after your COVID-19 symptoms began.

What are the possible side effects?[1]

- Side effects of getting any medication through a vein could include: brief pain from inserting the needle, bleeding, bruising of the skin, soreness, swelling, and possible infection at the injection site.
- Some patients have experienced diarrhea.
- Sotrovimab may also cause infusion or allergic reactions. Tell your healthcare professional if you experience any of these symptoms: fever, chills, nausea or feeling sick, headache, difficulty breathing, chest tightness, fall or increase in blood pressure, swelling of the face, throat irritation, rash with hives, itching or an itchy rash, muscle pain, uneven heart-beat, low oxygen in blood, increased sweating, dizziness or light headedness.
- Sotrovimab is a newer medication and all possible side effects may not be known yet. If you experience a troublesome side effect or symptom not listed here that becomes bad enough to impact your daily activities, tell your healthcare professional.

What should I do if my COVID-19 symptoms get worse?[2]

- Monitor your health and call Health Link 811 or your healthcare provider if you have questions or concerns.
- **Call 911 immediately** if you experience severe symptoms of COVID-19, such as:
  • difficulty breathing • severe chest pain • feelings of confusion • loss of consciousness.

This treatment does not shorten your isolation times. It is important you continue to follow the isolation requirements given to you at the time of your positive test.

Information sourced on October 28, 2021 from:

1) Sotrovimab [product monograph]. Mississauga (ON): GlaxoSmithKline, Inc.; 2021 Jul 30 Sotrovimab Product Monograph (gsk.com)

2) Alberta.ca Symptoms and Testing: Symptoms and testing | Alberta.ca

Last Updated: 11/05/2021
ECC Approved: 11/08/2021

Alberta Health Services

Thank you.

For More information please contact:

COVID.MonoclonalAntibodyTherapy@albertahealthservices.ca.

Alberta Health Services